REMARKS

Claims 30-35 and 44-46 are pending in the subject application. Applicants have herein amended the specification to update the ATCC deposit information. This amendment does not involve any issue of new matter. Therefore, entry of this amendment is respectfully requested.

Rejection under 35 U.S.C. 112, first paragraph

The Examiner rejected claims 30-35 and 44-46 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner stated that elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. The Examiner stated that when biological material is required to practice an invention, and if it is not so obtainable or available, the enablement requirements of 35 U.S.C. '112, first paragraph, may be satisfied by a deposit of the material. The Examiner stated see 37 CFR 1.802. The Examiner stated that the specification does not provide a repeatable method for obtaining clone CD4-IgG2-pcDNA1 and it does not appear to be a readily available material. The Examiner stated that deposit of the clone would satisfy the requirements of 35 USC '112, first paragraph. The Examiner stated that it is noted that applicant has deposited the clone CD4-IgG2-pcDNA1 at ATCC (page 19 of the specification), but there is no indication in the specification as to public availability. The Examiner stated that if a deposit is made under the terms of the

Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. The Examiner stated see 37 CFR 1.808. The Examiner stated that applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. §1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination."

In response, applicants have hereinabove amended the specification to update the address for the ATCC and to include the dates for each of the deposits. In support, applicants attach hereto a copy of the ATCC deposit receipts for ATCC Designation Nos. 40949-40952 (**Exhibit B**) and ATCC Designation Nos. 75192-75194 (**Exhibit C**).

Plasmids CD4-IgG2-Rf (ATCC Designation No. 40949), CD4-IgG1-Rf (ATCC Designation No. 40950), CD4-IgG1-pcDNA1 (ATCC Designation No. 40951), and CD4-IgG2-pcDNA1 (ATCC Designation No. 40952) were received on January 31, 1991 and were accepted by the American Type Culture Collection (ATCC), 10801 University Blvd., Manassas, VA 20110-2209. Plasmids CD4-IgG1HC-pRcCMV (ATCC Designation No. 75192), CD4-IgG2HC-pRcCMV (ATCC Designation No. 75193) and CD4-kLC-pRcCMV (ATCC Designation No. 75194), were received on January 30,

1992 and were accepted by the American Type Culture Collection (ATCC), 10801 University Blvd., Manassas, VA 20110-2209. The ATCC is an International Depository Authority recognized under the provisions of the Budapest Treaty. All restrictions upon public access to these deposits will be irrevocably removed upon the grant of a patent on the subject application. The deposits will be replaced if viable samples cannot be dispensed by the ATCC.

Applicants contend that these amendments and remarks obviate the above objection and respectfully request that the Examiner reconsider and withdraw this ground of objection.

Rejection under 35 U.S.C. 103(a)

The Examiner rejected claims 30-35 and 44-46 under 35 U.S.C. 103(a) as being unpatentable over Capon, US Patent 5,565, 335, for the reasons of record in the Office Action of August 07, 1997 (Paper #20). The Examiner stated that applicants arguments have not been found persuasive for the reasons for record and the following reasons. The Examiner stated that applicants argue the criticality of the specific amino acid composition and structure of the CD4 portion and of the Ig portion of their chimera, and that Capon teaches away from the claimed construct. The Examiner stated that however, this is not persuasive because, while Capon's preferred embodiment does not have the exact structure claimed herein, the Capon reference was not applied in order to anticipate the claims, but has been applied to render the claims obvious, and Capon clearly envisions making chimeras using modified CD4 and immunoglobulin chains 9see for example col.5, lines 26-32), teaches a CD4-IgG2 fusion protein (col.7, lines 47-49) and does not teach

away from the claimed invention. The Examiner stated that applicants argue that their construct has unexpected properties, and refer to Exhibits 1 and 2. The Examiner stated that however, this argument cannot be considered, absent evidence being properly presented. The Examiner stated that if applicants wish to provide evidence for consideration by the Patent Office, applicants must provide a declaration according to Rule 1.132. The Examiner stated that applicant argue that their CD4-gamma2 chimeric heavy chain homodimer construct has unexpected properties, by referring to results published by Gauduin, Journal of Virology, 70(4):2586-2592, April 1996, and Capon, Nature 337:525-531, 9 February 1989, (Exhibits 3 and 4). The Examiner stated that Gauduin teaches a CD4-IgG2 construct that is more potent than sCD4 in ex-vivo neutralizing HIV-1 and Capon (Nature) teaches that sCD4 and CD4-IgG1 are equipotent in neutralization. The Examiner stated that applicants therefore concludes that "CD4-gamma2 is more potent than CD4-gamma1". The Examiner stated that however, this is not persuasive, because applicants, in the specification and in their arguments against the Capon '335 patent, insist upon the criticality of the specific amino acid composition and secondary structure of their chimera for its function. The Examiner stated that the examiner could not clearly ascertain if the claimed CD4-gamma2 chimeric heavy chain homodimer, and "CD4-IgG2, a tetrameric human antibody prepared from a human IgG2 with replacement of each heavy- and light-chain variable region by the first and second domains of human CD4" disclosed by Gauduin, page 2586, col.2 lines 306, are identical in amino acid composition and structure/conformation, and therefore it is not clear if the activity of the claimed CD4-gamma2 chimeric heavy chain homodimer abnd of the cited CD4-IgG2 tetrameric antibody are identical or

comparable.

In response, applicants respectfully traverse the Examiner's above rejection. Applicants contend that the cited reference, namely U.S. Patent No. 5,565,335, issued to Capon does not render obvious the claimed invention. Applicants contend that Capon et al does not teach, suggest or disclose applicants' claimed invention. Accordingly, applicants request that the Examiner reconsider and withdraw this ground of rejection.

Summary

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the various grounds of objection and rejection and earnestly solicit allowance of the pending claims, i.e. claims 30-35 and 44-46.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invites the Examiner to telephone either of them at the number provided below.

No fee, other than the enclosed $445.00 fee for a three-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

9-10-01

John P. White Date
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